

II. REMARKS

Applicants acknowledge with appreciation the examiner's allowance of claims 1 and 7 as set forth in the January 14, 2004 final Office Action. Prior to amendment, claims 1-4 and 7-12 were pending in this application. Claims 2, 3 and 4 have been cancelled, claims 9 and 10 have been amended, and new claims 13-14 have been added herein. Claims 1 and 7-14 will be pending upon entry of this amendment to the final Office Action. Originally submitted claim 2 stands rejected under 35 U.S.C. §112 second paragraph. Previously added claims 8 and 10-12 were withdrawn from consideration as allegedly being directed to an invention that is independent or distinct from the originally claimed invention.

A. The Amendments

Applicants have cancelled claim 2-4 and added two new independent claims 13-14. The new claims incorporate all of the limitations of the cancelled claims 2, 3 and 4, and are presumed to be in condition for allowance per Examiner's suggestion on page 4 of the Office Action. Claim 10 has been amended to recite the same features as the "label" of elected original claim 1. Applicants submit that with this amendment, claim 10 is properly included with the elected claims. The amendments and new claims are fully supported in the application as filed and no new matter is added hereby. Entry of these amendments under 37 C.F.R. §1.116 (b) is proper as the amendments comply with suggestions of the Examiner and/or put the claims in condition for allowance or better condition for appeal, and Applicants respectfully request that the amendments be entered in the application.

B. Withdrawal of newly submitted claims 8 and 10-12.

In the final Office Action, dated January 14, 2004, claims 8 and 10-12 were withdrawn from consideration as allegedly being directed to an invention that is independent or distinct from the invention originally claimed. Office Action at page 2. It was asserted that the method of preparation of claim 8 did not prepare either the contents of the "single vessel" of original claim 1 (containing NHS, carbodiimides and a label) nor the contents of the "single vessel" of original claim 7 (containing a label derivatized with a heterofunctional reagent and a means for activating the reagent). *Id.* It was further asserted that the method of preparation of claim 8 requires the "sequestration" of reagents and "step for releasing sequestration" did not necessarily

imply a “dry form” of the reagents of claim 1 and 7. Finally it was asserted that claim 8 was distinct from the originally examined claims for the reason that different patentability considerations would be involved in addressing a method of preparation which does not prepare the products already examined. *Id.*

Applicants respectfully traverse the withdrawal of claim 8 from consideration as distinct and independent invention from the originally claimed invention because claim 8 retains the subject matter of previously cancelled originally submitted claim 5. In a previous Office Action of July 30, 2003 the original claim 5 was rejected under 35 U.S.C. §112 first and second paragraphs, as allegedly failing to comply with the enabling written description requirement. In Applicant’s response letter of October 27, 2003 to that Office Action, Applicants cancelled claim 5 and added new claim 8 as a “step for” claim with §112, sixth paragraph, limitations incorporating the subject matter of the cancelled claim 5 to provide clarity. As a “step for” claim under 35 U.S.C. §112, paragraph 6, claim 8 is drawn to the steps recited in the specification and equivalents thereof. Support for original claim 5 can be found in the Examples, and therefore the elements of claim 8 correspond to the elements of original claim 5 and equivalents. In particular, claim 8 recites steps as follows: (i) a “step for preparing a derivatized label” (see, *e.g.*, in original claim 5 “a. derivatizing a label by reaction with one functionality of a heterofunctional reagent”); (ii) a “step for preparing a container” (see, *e.g.*, in original claim 5 “b. placing derivatized label in a container”); (iii) a “step for releasing sequestration” (see, *e.g.*, in original claim 5 “c. hydrating label and activating reagent”); and (iv) a “step for releasing sequestration of said derivatized label to permit reaction” (see, *e.g.*, in original claim 5 “d. removing the activating reagent”). Therefore, Applicants respectfully request that the Examiner reconsider withdrawal from consideration of claim 8, and examine it to the extent that it contains the same subject matter as originally submitted claim 5.

Further, it was asserted that the “single vessel” of newly presented claim 10 contained a different set of components than those present in the “single vessels” of original claims 1 and 7. *Id.* It was asserted that the “label” of claim 10 was not required to contain either an amine or a carboxyl group as required by claim 1. Applicants have amended claim 10 by adding the limitation “either an amine or a carboxylic moiety” of the label so that the label of claim 10

corresponds to the label of claim 1. Applicants respectfully traverse the withdrawal of claims 8 and 10-12 from consideration.

Applicants would like to point out that the Office Action has not made a formal restriction requirement under 35 U.S.C. §121 relating to the claims at issue. Although the examiner has cited 37 CFR 1.142(b) and MPEP 821.03 in withdrawing the added claims 8 and 10-12 that were added by amendment following an Office Action, Applicants believe that a recent Federal Circuit decision, Geneva Pharmaceuticals Inc. v. Glaxo SmithKline PLC, 349 F.3d 1373, [68 U.S.P.Q.2d 1865] (Fed. Cir 2003), has implicitly required examiners to formally restrict these newly added claims following an office action if these new claims are believed to be drawn to a distinct invention from the invention previously claimed. In this case, the applicants (Glaxo SmithKline) of the '035 application filed an amendment adding a single method of use claim. The '035 application was under examination by a different examiner (Goldberg). *Id.* at 7. The applicants stated that examiner (Berch) considered the added claim separate and distinct from the claims of the '007 application. *Id.* Further, examiner Berch held that the instant method-of-use claim was separate and patentably distinct from the compound and indicated that the claim should be submitted in the instant divisional application. *Id.* However, the record showed no examiner response to the statement. *Id.* Accordingly the Circuit court held that the applicant's uncorroborated statement did not adequately document with sufficient clarity that the PTO required restriction. *Id.* Further, the court held that §121 only applies to a restriction requirement that is documented by the PTO in enough clarity and detail to show consonance. *Id.* The restriction document must identify the scope of the distinct inventions that the PTO has restricted, and must do so with sufficient clarity to show that a particular claim falls within the scope of the distinct inventions. *Id.* Therefore, unless claims 8 and 10-12 are examined, Applicants respectfully request a formal restriction requirement under §121 with sufficient clarity to show that claims 10-12 falls within the scope of the distinct inventions rather than informally stating that claims 8 and 10-12 are directed to an invention that is independent or distinct from the invention originally claimed.

Finally, Applicants amendment of the claims addresses all of the remaining issues that were raised in the Office Action.

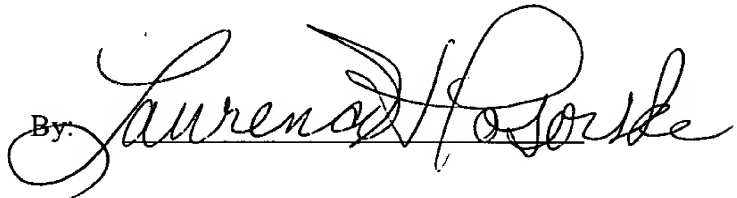
REQUEST FOR ALLOWANCE

Applicants earnestly solicit reconsideration of the application in view of these remarks. Applicants respectfully submit that in view of the above amendments and remarks, this application is in condition for allowance and respectfully request an early notification of allowance for the claims as amended herein. If any further action is necessary to place this application in condition for allowance, Applicants would appreciate a telephone call to the undersigned counsel to resolve such issues in an expeditious and effective manner.

Respectfully submitted,

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